

CHAPTER 33-03-31

CERTIFICATE OF PUBLIC ADVANTAGE

Section

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33-03-31-01. Definitions. Unless otherwise defined, or made inappropriate by context, all words used in this chapter have the meanings given to them under North Dakota Century Code chapter 23-17.5, except:

1. "Applicant" or "applicants" means the party or parties to a cooperative agreement for which a certificate of approval is sought under this chapter.
2. "Certificate" means a certificate of public advantage issued under this chapter.
3. "Competition" means that state of the relevant market in which individual buyers and sellers do not influence price by their purchases or sales.
4. "Relevant geographic market" means that geographic area from which the applicants traditionally draw significant patronage in the relevant product market, or, in the case of a new product, that area from which the applicants may reasonably anticipate significant patronage.
5. "Relevant product market" means a product or group of products offered by the applicants under the cooperative agreement and all products or groups of products that a reasonable health care consumer would find to be acceptable substitutes.

History: Effective October 1, 1993; amended effective June 1, 1994.

General Authority: NDCC 23-01-03, 28-32-02

Law Implemented: NDCC 23-17.5-01

33-03-31-02. Administration by state health officer. The state health officer or, if appropriate, the officer's designee shall administer the provisions of this chapter.

History: Effective June 1, 1994.

General Authority: NDCC 23-01-03, 28-32-02

Law Implemented: NDCC 23-17.5

33-03-31-03. Application, filing fee, and prefiling procedure.

1. **Form and content of application.** The applicants may submit an application in whatever form or content they deem appropriate, subject only to the requirements of this section. The application must be supported by sufficient information and documentation to meet the applicants' burden of proof with respect to the standards for certification set forth in North Dakota Century Code section 23-17.5-03.
2. **Minimum application requirements.** An application for a certificate must include:
 - a. The exact name of each applicant, type of business organization, and the address of each applicant's principal business office.
 - b. For each applicant, the name, address, and telephone number of the person authorized to receive notices and communications with respect to the application.
 - c. A description of the nature and scope of the cooperation in the agreement.
 - d. A description of any consideration passing to any party under the agreement.
 - e. A proposed plan for postcertificate monitoring and active supervision by the department. This proposed plan must include:
 - (1) A description of the standards and criteria by which the benefits and disadvantages of the agreement may be measured. These may include the standards and criteria used by the applicable professional accreditation or certification agencies or bodies. It is preferred that any standards and criteria measuring quality focus on patient or client outcomes.
 - (2) A description of the information and the format for reports to be submitted periodically to the department sufficient to permit the department to evaluate whether performance by the applicants under the cooperative agreement is consistent with state policy as expressed in North Dakota Century Code chapter 23-17.5.
 - (3) A schedule setting forth the dates on which the compliance information will be periodically submitted to the department.
 - f. A copy of the cooperative agreement.

9. A verified statement by an authorized officer of each applicant attesting to the accuracy of the information contained in the application.
3. **Optional information and documentation to meet burden of proof.** The information and documentation in support of the application will vary with the subject matter of the cooperative agreement and the nature of the activities of the applicants. The applicants may consult with department and attorney general staff prior to filing the application for assistance in determining what supporting information and documentation may be useful in evaluating the application.
- a. Reduction in competition. The following items are examples of information and documentation that may assist the department and attorney general in evaluating the reduction in competition resulting from a cooperative agreement:
 - (1) A list of the services or products that are the subject of the proposed cooperative agreement.
 - (2) A list of the services or products that are necessarily connected or offered with the services or products that are the subject of the proposed cooperative agreement.
 - (3) A description of the geographic territory that will be served under the cooperative agreement.
 - (4) If the geographic territory described in paragraph 3 is different from the territory in which the applicants have offered these services or products over the last five years, a description of how and why it differs.
 - (5) A list of all products or services that a substantial share of the users of the products or services to be provided under the cooperative agreement would consider substitutes for those products or services.
 - (6) Identification of whether the services or products of the cooperative agreement are currently being offered or are reasonably capable of being offered by other providers in the geographic territory described in paragraph 3 and, if so, a list of those providers.
 - (7) A list of the steps necessary, under current market and regulatory conditions, for a third party to enter the geographic territory described in paragraph 3 and compete by offering the same or similar services or products.

- (8) A description of how the cooperative agreement will affect competition in the geographical territory over the life of the cooperative agreement.
 - (9) Copies of all business proposals, consultant reports, and feasibility studies used in the development of the proposed cooperative agreement.
 - (10) A description of the previous history of dealings between the parties.
 - (11) A pro forma statement of projected financial performance under the cooperative agreement.
 - (12) An explanation of how the cooperative agreement will affect the product and geographical markets to be serviced.
 - (13) An explanation of the projected effects of the cooperative agreement on each applicant's current business.
 - (14) An estimate of the market share of the applicants before and after the cooperative agreement regarding the services or products that are the subject of the cooperative agreement.
 - (15) A statement of why the services or products would not be provided at anticipated levels of price, availability, or quality in a competitive market.
 - (16) A description of other anticipated effects of the cooperative agreement. In this description, the applicant may include information possessed by the applicants or otherwise available to them regarding:
 - (a) Current and anticipated demand for the affected products or services.
 - (b) Current and anticipated capacity within the market to supply the services or product.
- b. Likely benefits to health care consumers. The following items are examples of information and documentation that may assist the department and the attorney general in evaluating the likely benefits to health care consumers from a cooperative agreement:
- (1) An explanation of the anticipated effect of the cooperative agreement on costs, including:

- (a) Pro forma financial statements showing the effect of the cooperative agreement on the cost of services or products that are the subject of the application.
 - (b) The intentions of the parties regarding the extent to which the projected cost savings will be passed on to the public. This explanation may include any undertaking by the applicants regarding their pricing for the services or products that are the subject of the application.
 - (c) The intentions of the applicants regarding the pricing of other services or products as a result of the cooperative agreement that is the subject of the application.
- (2) An explanation of how the cooperative agreement will affect availability of health care services or products, including:
 - (a) Information showing the relationship between the price of products or services and the demand for the products or services.
 - (b) New sales or service outlets to be established.
 - (c) Identity of target populations to be served by the cooperative agreement.
 - (d) Identity of populations currently being served by the applicants.
 - (e) Expected reductions, if any, in the availability of health care services and products to some populations, and how, in the view of the applicants, those reductions are compensated for by increases in the availability of health care services and products to other populations.
- (3) An explanation of how the cooperative agreement will increase the quality of health care. It is preferred that the application address quality issues in terms of patient or client outcomes and the standards and criteria used by the applicable professional accreditation or certification agencies or bodies or any other generally accepted quality measures. For example, a hospital may include:
 - (a) Patient morbidity and mortality.
 - (b) Periods required for convalescence.
 - (c) Number of patient days in the hospital.

- (d) The ability of medical staff to attain needed experience and the frequency of treatment necessary to better outcomes.
 - (e) Patient and family satisfaction.
 - (f) Number of readmissions for the same condition.
 - (g) Any other features which are likely to increase the quality of health care.
- 4. **Limited waiver of time limit.** If the department determines that the information submitted by an applicant is unclear, incomplete, or insufficient on which to base a decision, the department may request the applicant to augment or supplement the original filing. In the event the department requests that the applicants augment or supplement the original filing, the applicants may, by written notice to the department, waive the benefit of the ninety-day review time limit and extend the review period for an additional period not to exceed ninety days unless a longer extension of the review period is agreed to by the applicants and the department.
- 5. **Filing fee.** Except as provided in subsection 6, the application must be accompanied by a fee equal to the maximum assessment permitted by North Dakota Century Code chapter 23-17.5.
- 6. **Prefiling procedure.**
 - a. Prior to filing an application, potential applicants may submit to the department a request for determination of filing fee. This request must be accompanied by a detailed summary of the proposed application and a fee of two thousand dollars. This fee must be credited against the filing fee if the application is timely filed. In the event the potential applicants choose not to file the application, this fee is not refundable.
 - b. The department shall review the detailed summary of the proposed application and determine the amount of filing fee based upon the anticipated costs of review of the application and active supervision of the certified agreement. No later than twenty days following receipt of a request for determination of filing fee, the department shall notify the applicants of the amount of the filing fee. In no event may this amount exceed the maximum assessment permitted by North Dakota Century Code chapter 23-17.5. The notice must allocate the amount of the filing fee between the anticipated costs of review of the application and the costs of active supervision of the certified agreement.

- c. The filing fee determined under this subsection is effective if the application is filed within one hundred eighty days after notice of the amount of the filing fee. Upon filing the application, the applicants shall pay that portion of the filing fee allocated to the costs of review of the application, less the two thousand dollars previously paid. Upon approval of the application, the applicants shall pay that portion of the fee allocated to the costs of active supervision of the certified agreement. Failure to pay the balance of the fee within thirty days of approval of the application renders the certificate void. In the event the application is denied, the applicants shall not be obligated to pay the balance of the fee allocated to the costs of active supervision. In the event the department determines that the application filed is not substantially the same as that described in the summary, the department may assess an additional filing fee by notice to the applicants. The additional filing fee must be paid within thirty days of the notice.

History: Effective June 1, 1994.

General Authority: NDCC 23-01-03, 28-32-02

Law Implemented: NDCC 23-17.4-03, 23-17.5-02, 23-17.5-11

33-03-31-04. Notice and hearing.

1. **Notice of hearing.** Upon filing of the application and payment of the application fee and at least twenty days prior to the date set for hearing, the department shall provide the applicants with written notice of the time and place for the public hearing on the application. The department shall also, within that period, publish a notice of hearing in the official newspapers of all counties where any of the applicants have a principal place of business and all counties in which the applicants plan to do business under the cooperative agreement. The published notice must include sufficient information to advise the public of the nature of the cooperative agreement and must invite written comments and oral testimony from the public at the public hearing.
2. **Public hearing.** The public hearing must be conducted by an independent hearing officer under article 98-02. If requested by the department the hearing officer shall prepare a recommended decision, including finds of fact, conclusions of law, and a proposed order approving the application, not approving it, or approving it subject to terms and conditions.

History: Effective June 1, 1994.

General Authority: NDCC 23-01-03, 28-32-02

Law Implemented: NDCC 23-17.5-02

33-03-31-05. Departmental review.

1. **Decision.** The department shall issue a decision consisting of findings of fact and conclusions of law on the application for a certificate and an order either approving the application, not approving it, or approving it subject to terms and conditions. The decision of the department must be based upon the record, which must consist of all information and documentation filed with the department by the applicants and any interested persons in the proceeding, including responses to the department's information requests and testimony presented at the public hearing.
2. **Criteria applicable to applications.** North Dakota Century Code section 23-17.5-03 sets forth the standards by which the department is to measure whether the likely benefits to health care consumers resulting from the cooperative agreement outweigh any disadvantages attributable to a reduction in competition that may result from the agreement.
 - a. Potential benefits. In evaluating the potential benefits to health care consumers from a cooperative agreement, the department may consider the following criteria:
 - (1) Enhancement of the quality of health care services. The department may consider the likely effect of the cooperative agreement on patient or client outcomes. The department may consider the standards and criteria used by the applicable professional accreditation or certification agencies or bodies or any other generally accepted quality measures.
 - (2) Geographical proximity of health care facilities to the communities traditionally served. The department may consider the extent to which the cooperative agreement is likely to:
 - (a) Make a new health care service or product available in a particular geographic area.
 - (b) Prevent the closing or substantial downsizing of a health care facility or the elimination or reduction of a health care service that would otherwise be likely to occur without the cooperative agreement.
 - (c) Preserve health care facilities or services in one community at the expense of health care facilities or services in another community.
 - (3) Gains in cost efficiency. The department may consider the extent to which the proposed cooperative agreement is likely to result in:

- (a) Any cost savings to the applicants.
 - (b) Any cost savings being passed on to the health care consumer.
 - (c) Cost shifting through higher prices to other payers or purchasers of other products and services.
 - (d) Reduced costs of regulation, both for the state and the applicants.
 - (e) Any other result likely to reduce costs to health care consumers.
 - (f) The extent to which any cost savings will be obtained at the expense of a degradation of the quality of medical products or services.
- (4) Improvements in the utilization of health care resources and equipment.
- (5) Avoidance of duplication of health care resources. The department may consider:
- (a) The extent to which the same or substitute products or services are available in the same community or geographic market.
 - (b) Any excess capacity in the provision of the same or substitute products and services existing within the same community or geographical market.
- b. Potential disadvantages. In evaluating the disadvantages attributable to a reduction in competition that may result from a cooperative agreement, the department may consider:
- (1) The relevant product and geographic markets to which the agreement will be administered. In determining the relevant markets, the department may take into account elasticities of supply and demand and the ability of a hypothetical monopolist to profitably reduce output and increase price in a small but significant and nontransitory manner.
 - (2) The existing market shares in the relevant product and geographic markets of the applicants, as well as any other parties operating within those markets.

- (3) The presence of actual or potential market entrants and ease or difficulty of market entry into the relevant product and geographic markets.
 - (4) Whether or not the agreement results in the creation of a new product or one previously unavailable in the relevant geographic market.
 - (5) The reasonably anticipated effect of the agreement on existing market structure.
 - (6) The ways, if any, the agreement will promote competition in the relevant product and geographic markets.
- c. Conflict between objectives. In the event there is a conflict between or among the statutory standards for certification when applied to an application, the department shall address the conflict in its decision and state the reasons supporting the manner in which the department resolves the conflict.

History: Effective June 1, 1994.

General Authority: NDCC 23-01-03, 28-32-02

Law Implemented: NDCC 23-17.5-02, 23-17.5-03

33-03-31-06. Active supervision of certified agreements.

1. The order approving the application must set forth a plan for postcertificatemonitoring and active supervision of the activities of the parties under the certified cooperative agreement. The plan must include:
 - a. A description of the standards and criteria by which the actual benefits and disadvantages of the agreement may be measured.
 - b. A description of the information and the format for reports to be submitted periodically to the department sufficient to ensure that performance by the parties under the certified agreement is in accord with the state policy as expressed in North Dakota Century Code chapter 23-17.5.
 - c. A schedule setting forth the dates on which the information and reports determined under subsection 2 will be submitted to the department.
2. The department shall publish notice in the official newspapers of all counties where any of the applicants have a principal place of business and of all counties in which the applicants do business under the cooperative agreement. This notice must be published two years after the date of the issuance of the certificate and at two-year intervals

thereafter for as long as the certificate remains subject to active supervision by the department. This notice must solicit comments from the public concerning the impact the cooperative agreement has had on the cost, quality, and availability of medical products or services.

History: Effective June 1, 1994.

General Authority: NDCC 23-01-02, 28-32-02

Law Implemented: NDCC 23-17.5-04

33-03-31-07. Certificate modification. At any time after the certificate of public advantage has been issued, the terms and conditions of the certificate may be modified by agreement between the applicants and the department. Before agreeing to modify any certificate, the department shall publish notice of the proposed modifications in the official newspapers of all counties in which any of the parties to the certified agreement have a principal place of business and of all counties in which the parties do business under the cooperative agreement. The notice must contain an explanation of the proposed modification and invite comments on the proposed modification. Upon motion of the parties or upon its own motion, the department may hold a public hearing on the proposed modification. A modification agreement becomes effective thirty days following the later of the date of the public notice or the public hearing, if any.

History: Effective June 1, 1994.

General Authority: NDCC 23-01-03, 28-32-02

Law Implemented: NDCC 23-17.5

33-03-31-08. Certificate termination.

1. **Grounds for termination.** After notice and hearing, the department may terminate a certificate of public advantage if it is found to be more probable than not that:
 - a. The applicants have failed to comply with material terms or conditions of the certificate of public advantage;
 - b. The applicants have failed to perform the terms and conditions of the cooperative agreement as represented to the department at the time of the application; or
 - c. The likely or actual benefits to health care consumers from the cooperative agreement no longer outweigh the disadvantages attributable to a reduction in competition resulting from the agreement.
2. **Complaint.** If it appears that any of the grounds for certificate termination exist, the department or the attorney general may initiate administrative proceedings to revoke a certificate of public advantage by serving upon the applicants a copy of a complaint alleging sufficient facts to support termination of the certificate.

3. **Procedure.** Proceedings to terminate a certificate of public advantage are a contested case proceeding subject to the procedure set forth in North Dakota Century Code chapter 28-32.

History: Effective June 1, 1994.

General Authority: NDCC 23-01-03, 28-32-02

Law Implemented: NDCC 23-17.5-04